

REMARKS

1. Declaration

A substitute Declaration was filed on May 26, 2005. Applicants request that the acceptability of the substitute Declaration be acknowledged.

2. Specification

As requested in the Office Action, the specification has been amended to remove references to an embedded hyperlink and to identify a trademark by generic terminology. No new matter has been added by these amendments.

3. Claims

Claims 1, 3, 4, 7 and 10–13 have been examined. Claims 1, 3, 4, 7 and 10–13 stand rejected under 35 U.S.C. § 112, ¶2; Claims 1, 3 and 4 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,613,512 or U.S. Patent No. 6,524,790 (collectively “Kopf” in light of their duplicate disclosure); Claim 7 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Kopf in view of J. Microscopy, 197(2) 2/2000, 136–149 (“Squire”); and Claims 10–13 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Kopf in view of Cytometry, 40:102–108, 2/2000 (“Armstrong”). Claim 13 stands objected to because of an informality.

a. § 112 Rejections

Several amendments have been made to the claims to overcome the § 112 rejections. In particular, to address the concern that Claim 1 is vague and indefinite, the preamble has been amended to distinguish between the characteristic parameter of an analyte, which is intrinsically independent of a flow velocity of the analyte, and a measurement of the characteristic parameter of the analyte, which is capable of being influenced by or dependent on

the velocity of the analyte. That is, the recited method is concerned with determining the intrinsic characteristic parameter under circumstances where an apparent velocity dependence is introduced by measurement conditions (*see, e.g.*, Application, page 2, lines 7–21). Amendments have been made to the body of the claim for consistency with this clarification.

The dependence of Claims 7 and 10 has been amended to address the § 112 rejections of those claims. In doing so, Claim 7 has incorporated limitations previously recited in cancelled Claim 6.

It is specifically noted that no new matter has been added by any of these amendments. For example, the Examiner's attention is drawn to the discussion in the application of the example of fluorescence intensity as a characteristic parameter. The application explains that fluorescence intensity may be quantified by "measuring the area underneath the [fluorescent] peak" after illuminating a uniform detection zone (*id.*, page 2, lines 15–17), but that this is a "velocity dependent measurement" (*id.*, page 2, line 17). That "[t]he total fluorescence intensity integrated over the excitation duration is [a] velocity dependent measurement" is again noted at page 7, lines 4–5. Determination of the fluorescence intensity independent of the flow velocity of the analyte may be performed in an embodiment using the method explained at page 7, lines 21–29:

By placing two different detection zones at a predetermined distance (i.e., "d") from each other, one can measure the velocity of the analyte flowing through the detection zones by measuring the time difference (i.e. "t") at which the analyte passes through the first detection zone and the second detection zone. Since the velocity (i.e. "v") is distance divided by time, the flow velocity of analyte is calculated by the formula: $v=d/t$, where v , d and t are those defined above. The peak area is then multiplied by the velocity (or simply divided by time since d is constant) to normalize the peaks, i.e. to eliminate the velocity factor. In this manner a more accurate determination of the analyte characteristic parameter can be made.

In this way, an objective in this embodiment of "significantly reduc[ing] or eliminat[ing] the [e]ffect of molecule velocity through a detection zone on the peak area by

eliminating or normalizing the velocity factor of the analyte characteristic parameter” (*id.*, page 7, lines 16–18) is achieved.

b. Prior Art Rejections

The prior-art rejections rely on a construction of Kopf as disclosing the measurement of the characteristic parameter within a fluid flow at a plurality of locations. Kopf describes the determination of a reaction rate through measurement of a concentration of products and reactants at a single selected position in a flow, and determining a velocity of a component of the flow (Kopf, column 2, lines 6–23). While the Office Action appears to acknowledge that the concentration is measured only at a single detection point (*see, e.g.*, Fig. 1 of Kopf and column 7, line 48, through column 8, line 17), the Office Action takes the position that this corresponds to measurement at a plurality of positions because Kopf “disclose[s] analyte measurement in a continuous flow channel while measuring a signal indicative of the analyte (characteristic parameter) at various time points (plurality of locations along the fluid flow channel)” (Office Action, page 10).

Such a construction, in which the plurality of locations is equated to a plurality of time points in a continuous flow, has been precluded by amending Claim 1 to recite that the characteristic parameter is measured “within the flow channel at a plurality of different detection zones separated along a flow path of the analyte.” Support for this limitation is provided in the Application at, *e.g.*, page 7, lines 18–21. Since Kopf is directed to a single detection point for measurement, it does not disclose “measuring the characteristic parameter . . . at a plurality of different detection zones separated along a flow path of the analyte.”

It is, thus, respectfully believed that Claim 1 is patentable and that each of the dependent claims is also patentable by virtue of their dependence from a patentable claim.

Application No. 09/970,453
Amendment dated July 22, 2005
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1641

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c. Claim Objection

Claim 13 has been amended as suggested in the Office Action. Certain other minor amendments have been made to the claims for purposes of clarification and for consistency with the amendments discussed above.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

Date: July 22, 2005


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